

## **REMARKS**

### **I. Status of the Application**

Claims 1 – 12 are pending in the application. Claims 1 – 12 were rejected under 35 U.S.C. § 112, first paragraph for not being enabling. Claims 1 – 12 stand rejected under 35 U.S.C. § 112, second paragraph for being indefinite. Claims 11 and 12 stand rejected under 35 U.S.C. § 101 for having improper form. Claim 1 – 3 stand rejected under 35 U.S.C. §102(b) as being anticipated by Japanese Patent 61181960 A.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention and to place the claims into condition for allowance. Claims 1 – 11 have been amended and claims 13 – 22 have been added. Support for the amendments to claims 1 – 6 can be found at least at page 4 lines 26 – 27. Support for claims 7 and 8 can be found, for example, at least at page 7 lines 6 – 11 and page 10 lines 27 – 29. Amendments to claims 9 – 11 find support in the specification at least at page 10 lines 27 – 29. Support for new claim 13 can be found at least at page 5 lines 10 – 12. Support for claim 13 can be found, for example, at page 5 lines 10 – 12. Support for new claim 14 can be found, for example at page 5 lines 15 – 16. Support for new claims 15 and 21 may be found, for example at page 4 lines 26 – 27. Support for new claims 16 and 21 may be found at least at page 5 lines 1 – 7. New claim 16 finds support, for example, at page 10 lines 22 – 25. Support for new claim 17 can be found, for example, at page 11 lines 14 – 20. Support for new claim 18 can be found at least at page 10 lines 12 – 17. New claim 19 finds support at least at page 9 lines 18 – 21. Claim 12 has been canceled without prejudice.

Applicants respectfully request entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

## **II. Claims 1 - 12 are Enabled Under 35 U.S.C. § 112, First Paragraph**

At page 2, paragraph 3 of the present Office Action, claims 1 – 12 are rejected under 35 U.S.C. § 112, first paragraph for not being enabling. The Examiner asserts that pharmacons are not clearly described. Applicants traverse the rejection.

Applicants respectfully point out that at page 4 line 26 to page 5 line 8 of the specification, the term pharmacon is described and examples of a pharmacon are given. Beginning, for example, at line 26 of page 4, pharmacon is described as being “understood to mean a biologically or pharmaceutically active substance.” In addition, Applicants submit that the term “pharmacon” is well known to one skilled in the art and is used in other United States Patents, including U.S. Patent Nos. 6, 399,566; 6,395,302; and 6,303,148.

Thus, Applicants’ claims are enabled. Accordingly, Applicants request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

## **III. Claims 1 – 12 are Definite Under 35 U.S.C. § 112, Second Paragraph**

At page 3, paragraph 1 of the present Office Action, claims 1 – 12 are rejected under 35 U.S.C. § 112, second paragraph for being indefinite. The Examiner asserts that claims 1 – 12 are indefinite because the claims contain a broad range or limitation together with a narrow range or limitation so that the metes and bounds of the claims are not clear. Applicants respectfully traverse the rejection as to the amended claims.

Applicants have amended claims 1 – 11 to more clearly define and claim their invention. The claims do not contain a broad limitation together with a narrow limitation.

Thus, Applicants' claims, in light of the amendments, are definite and meet the definiteness requirements under 35 U.S.C. § 112, second paragraph. Applicants respectfully request the rejection be withdrawn.

**IV. Claims 11 and 12 are Proper Process Claims Under 35 U.S.C. § 101**

At page 4, paragraph 2 of the present Office Action claims 11 and 12 have been rejected under 35 U.S.C. § 101 for having an improper definition of a process. The Examiner asserts that claiming a recitation of use without setting forth any steps involved in the process results in an improper definition of a process. Applicants traverse the rejection as to the amended claims.

Applicants have amended claims 11 to conform to proper process claim form. Claim 12 has been canceled without prejudice.

Thus, Applicants' claims, in light of the amendments, are in proper form and conform to 35 U.S.C. § 101. Applicants respectfully request the rejection be withdrawn.

**V. Claims 1 – 3 are Not Anticipated by JP 61181960 A**

At page 4, paragraph 3 of the present Office Action, claims 1 – 3 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Japanese Patent No. JP 61181960 A (the JP 61181960 patent). The Examiner asserts that the JP 61181960 patent teaches inulin with the requisite degree of polymerization and would inherently be in a sugar glass state. The Examiner also asserts that the claims are directed only to the compound inulin. Applicants respectfully traverse this rejection.

Applicants' claims as amended are directed to a pharmacons incorporated into a fructan having a number-average degree of polymerization of at least 6 in the form of a sugar glass. As stated in the specification at page 7, lines 6 – 14, the solution of fructan (inulin in this example) containing a pharmacon is dried such that the pharmacon is “surrounded by a protective coating of amorphous inulin.” In other words, the pharmacon “is enclosed in an inulin glass, each pharmacon molecule is provided with a coating of amorphous inulin.” (Page 7, lines 23 – 26 of the specification). The JP 61181960 patent fails to teach or suggest the combination of a fructan with a pharmacon. In fact, the JP 61181960 teaches the combination of its fructan with an inorganic carrier, which is not a pharmacon as applicants have claimed.

In addition, the JP 61181960 patent teaches a polysaccharide over a full porous carrier wherein the polysaccharide has a number-average degree of polymerization of 10 – 500. There is no reasonable basis for the Examiners assertion that a polysaccharide having a number-average degree of polymerization of 10 – 500 is inherently in a sugar glass state. As applicants have described in the specification, at least at page 3, lines 14 – 23, special requirements are imposed on the drying procedure of fructans so as to prevent crystallization and promote sugar glass formation. It is not clear, nor is there a reasonable basis to assume from the JP 61181960 patent whether these special procedures are followed.

In response to the Examiner's statement that the claims are directed only to the compound inulin, Applicants respectfully point out that the Examiner has not made a § 112 written description rejection stating that fructan is not fully supported or described. Applicants assert, however, that they have fully described and enabled the genus of fructan. For example, see page 5 line 9 to page 6 line 28 of the specification where Applicants disclose that “a fructan is understood to mean any oligo- or polysaccharide which contains a plurality of anhydrofructan

units.” The specification goes on to describe the types of bonds contained in fructans and gives guidance on how to choose a suitable fructan for a particular purpose. The specification then provides inulin as a working example of a suitable fructan.

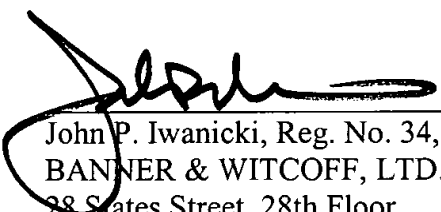
Thus, the JP 61181960 patent fails to teach all of Applicants’ claim limitations, and the claims cover the full scope of the term fructan. Accordingly, Applicants respectfully request that the rejection of claims 1 – 3 under 35 U.S.C. § 102(b) be withdrawn.

**VI. Conclusion**

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants’ attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 720-9600.

Respectfully submitted,

Dated: June 18, 2003

  
John P. Iwanicki, Reg. No. 34,628  
BANNER & WITCOFF, LTD.  
28 States Street, 28th Floor  
Boston, MA 02109  
617-720-9600